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FILING DATE.**

APPLICATION NUMBER: 60/494,463

FILING DATE: August 11, 2003

RELATED PCT APPLICATION NUMBER: PCT/US04/19491



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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)					
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<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max) PUSH-PULL NEEDLELESS INJECTOR					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number		27,792		<div>Place Customer Number Bar Code Label here</div>	
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification	Number of Pages	6	<input type="checkbox"/> CD(s), Number		
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	2	<input type="checkbox"/> Other (specify)		
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees				FILING FEE AMOUNT (\$)	
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:		08-0114		\$160.00	
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

SIGNATURE

Date

08/11/2003

TYPED or PRINTED NAME

WALTER A. HACKLER

REGISTRATION NO.

27,792

(if appropriate)

Docket Number:

3033P

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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P19LARGE/REV05

PUSH-PULL NEEDLELESS INJECTOR

A push-pull needleless injector in accordance with the present invention generally includes a housing having a proximal and a distal end. A chamber is disposed within the housing at the distal end thereof and an injector head is disposed at the housing distal end and in fluid communication with the chamber. A vial is provided for containing a medicament with the vial being in fluid communication with the chamber through a one-way valve.

A piston is slidably disposed within the housing and includes a piston head slidably disposed within the chamber and a stem disposed in the housing proximal end. The piston head is fitted to the chamber in order to draw medicament from the vial into the chamber through the one-way valve upon movement of the piston from a first position to a second position and to force medicament through the injection head upon movement of the piston from the second position to the first position.

A spring is provided and may be disposed around the piston stem for forcing the piston from the second position to the first position.

The spring is compressed by a cocking grip which is slidably disposed over the housing proximal end and a sear is provided for releasably holding the piston in the second position with the spring compressed.

A trigger disposed in an operational relationship with the sear is provided for releasing the spring in order to drive the piston to the first position and force medicament through the injection head.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention may be more clearly understood with reference to the appended drawings of which:

Figure 1 is a perspective view of a push-pull injection in accordance with the present invention generally showing a housing, a vial for containment of a medicament, an injection head, a cocking grip and a trigger;

Figure 2 is a cross sectional view of the injector shown in Figure 1 more specifically showing a chamber disposed within the housing, a piston slidably disposed within the housing with a piston head fitted within the chamber, and having a stem with a spring disposed therearound along with a sear for holding the piston in a second position with the spring compressed;

Figure 3 is a cross sectional view similar to Figure 2 showing release of the piston with the spring forcing the piston head through the chamber in order to force medicament through the injection head; and

Figure 4 is a cross sectional view similar to Figures 2 and 3 showing cocking of the spring and withdrawal of medicament from the vial into the chamber for subsequent injection.

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DETAILED DESCRIPTION

With reference to Figure 1, there is shown a push-pull needleless injector 10 generally including a housing 12, an injection head 14, a vial 16 for containing a medicament, such as, for example, BOTOX®, a cocking grip 20 and a trigger 22.

As shown in Figures 2-4, the housing 12 includes a distal end 26 and a proximal end 28 with a chamber 30 disposed within the housing 12 at the distal end 26.

The injection head, which may be of conventional design, is disposed at the housing distal end 26 and is in fluid communication with the chamber 30.

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The vial 16 may support a replaceable container 34 containing a medicament, not shown, as hereinabove referenced and is in fluid communication with the chamber through a dip tube 36 and a one-way valve 38.

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A piston 40 is slidably disposed within the housing 12 and includes a piston head slidably disposed within the chamber 30 and a separately moveable stem 44 disposed in the housing 28. The piston head 42 is fitted within the chamber

30 in order to draw medicament from the vial 16 into the chamber 30 through the one-way valve 38 and dip tube 36 upon movement of the piston head from a first position, as shown in Figure 3, to a second position shown in Figure 4 the entry of fluid into the chamber being indicated by the arrow 50 in Figure 4.

Medicament is forced through the injection head 14 by movement of the piston head 42 from the second position, as shown in Figure 2, to the first position as shown in Figure 3 with the injected medicament being indicated by the arrow 52. A head 54 on the piston stem 44 couples the stem 44 in a slidable manner with the piston head 42 between a fore plate 60 and an aft plate 62 of the piston head 42.

As shown in Figures 2-4, the spring 66 disposed around the piston stem 44 between the aft plate 62 and an end plate 70 which is compressed by the cocking grip 20 which is slidably disposed over the housing proximal end 28. Reciprocal movement of the cocking grip causes compression of the spring, as illustrated in the figures. A sear is provided for releasably holding the piston 44 in the second position with the spring 66 compressed by engagement with the aft plate 62, as shown in Figures 2 and 3.

The trigger 22 is pivotally 76 disposed on a housing 12 and in an operational relationship with the sear 74 for releasing the spring 66 in order to drive the piston 42 along with fore plate 60 to the first position, thus ejecting a

metered dose of medicament determined by the chamber 30 volume.

Although there has been hereinabove described a specific
5 push-pull needleless injector in accordance with the present
invention for the purpose of illustrating the manner in which
the invention may be used to advantage, it should be
appreciated that the invention is not limited thereto. That
is, the present invention may suitably comprise, consist of,
10 or consist essentially of the recited elements. Further, the
invention illustratively disclosed herein suitably may be
practiced in the absence of any element which is not
specifically disclosed herein. Accordingly, any and all
modifications, variations or equivalent arrangements which may
15 occur to those skilled in the art, should be considered to be
within the scope of the present invention as defined in the
appended claims.

WHAT IS CLAIMED IS:

1. A push-pull needleless injector comprising:
 - a housing having a distal and a proximal end;
 - 5 a chamber disposed within said housing at the distal end thereof;
 - an injection head disposed at the housing distal end and in fluid communication with said chamber;
 - a vial for containing a medicament, said vial being
 - 10 in fluid communication with said chamber through a one-way valve;
 - a piston slidably disposed within said housing and having a piston head slidably disposed within said chamber and a stem disposed in the housing proximal end, said piston head
 - 15 being fitted to said chamber in order to draw medicament from said vial into said chamber through said one-way valve upon movement of said piston from a first position to a second position and to force medicament through the injection head upon movement of the piston from the second position to the
 - 20 first position;
 - a spring disposed around the piston stem for forcing said piston from the second position to the first position;
 - a cocking grip slidable disposed over the housing proximal end for compressing said spring;
 - 25 a sear for releasably holding said piston in the second position with said spring compressed; and
 - a trigger disposed in an operational relationship with said sear for releasing said spring in order to drive said piston to said first position.

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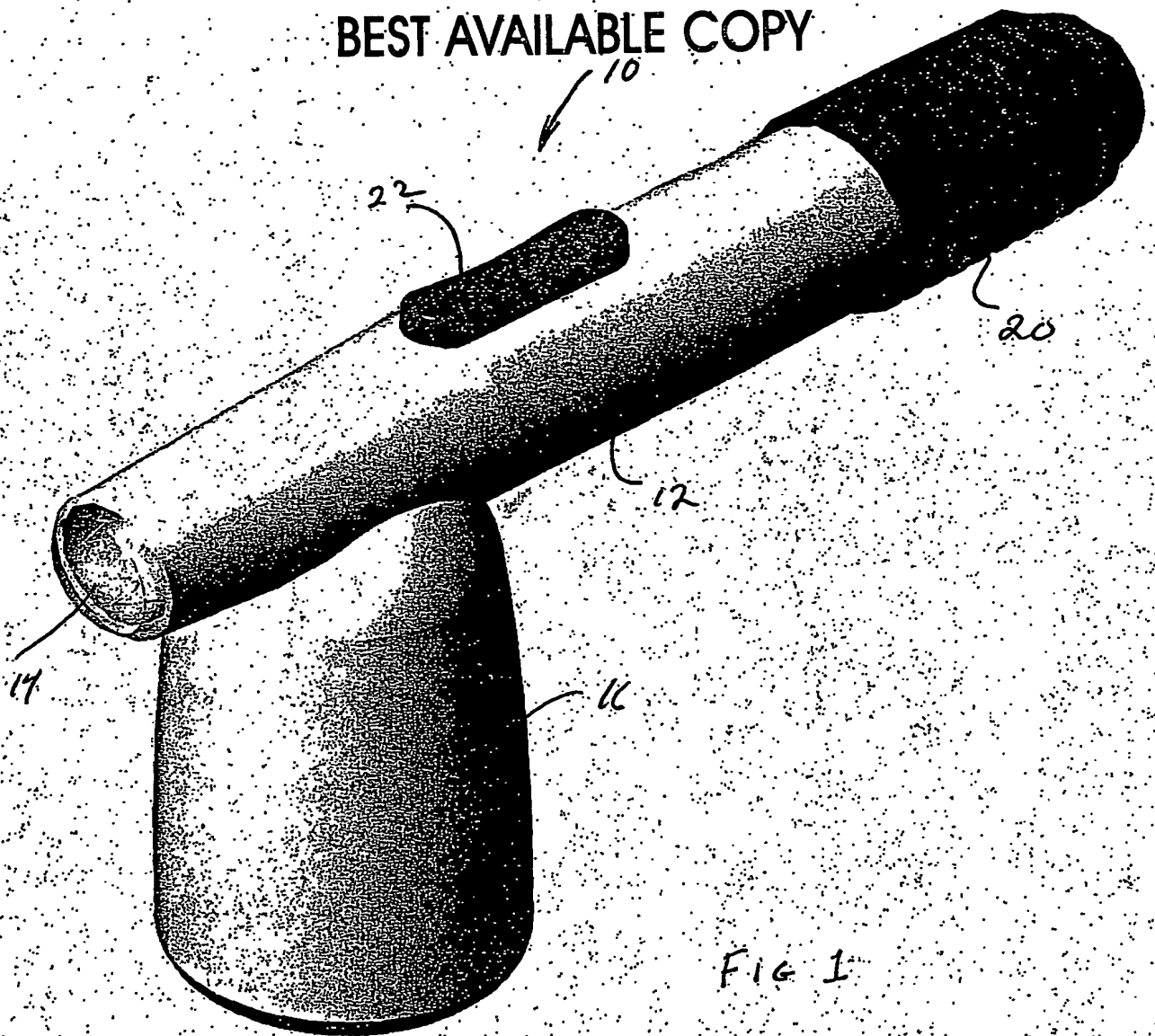


FIG 1

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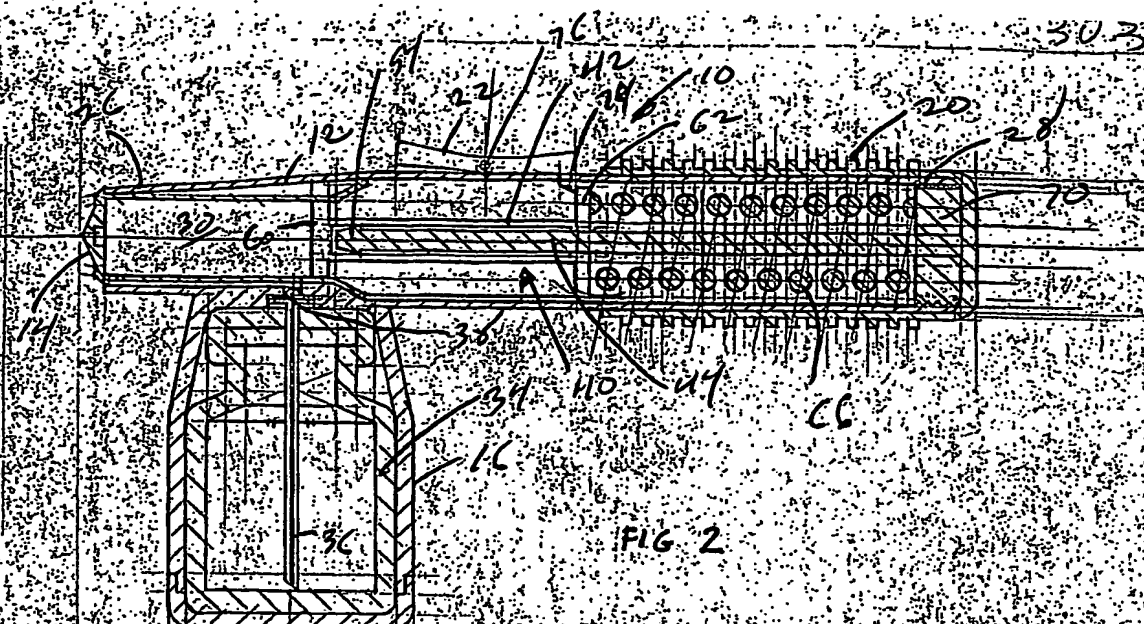


FIG 2

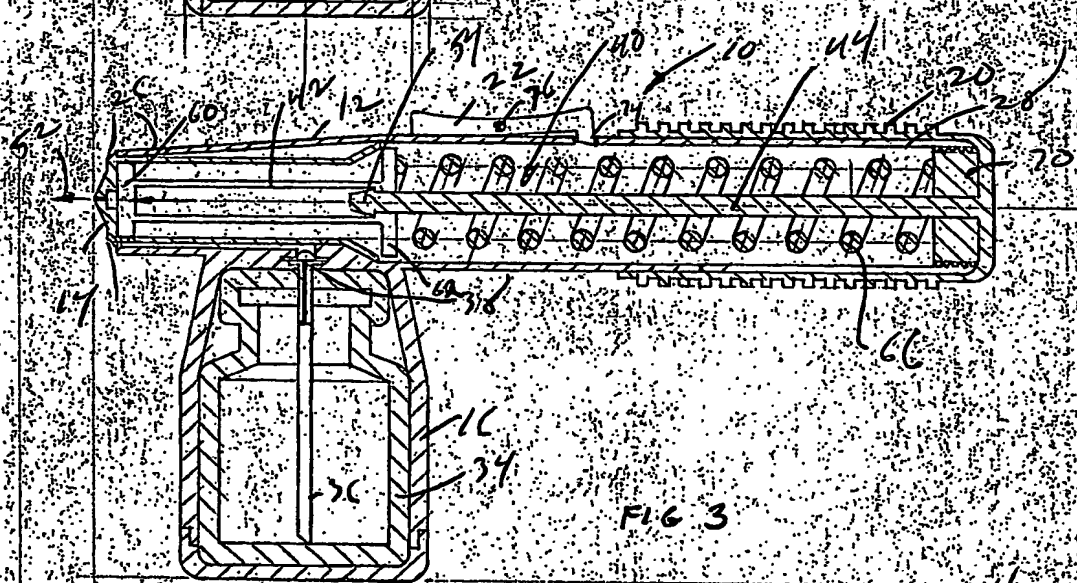
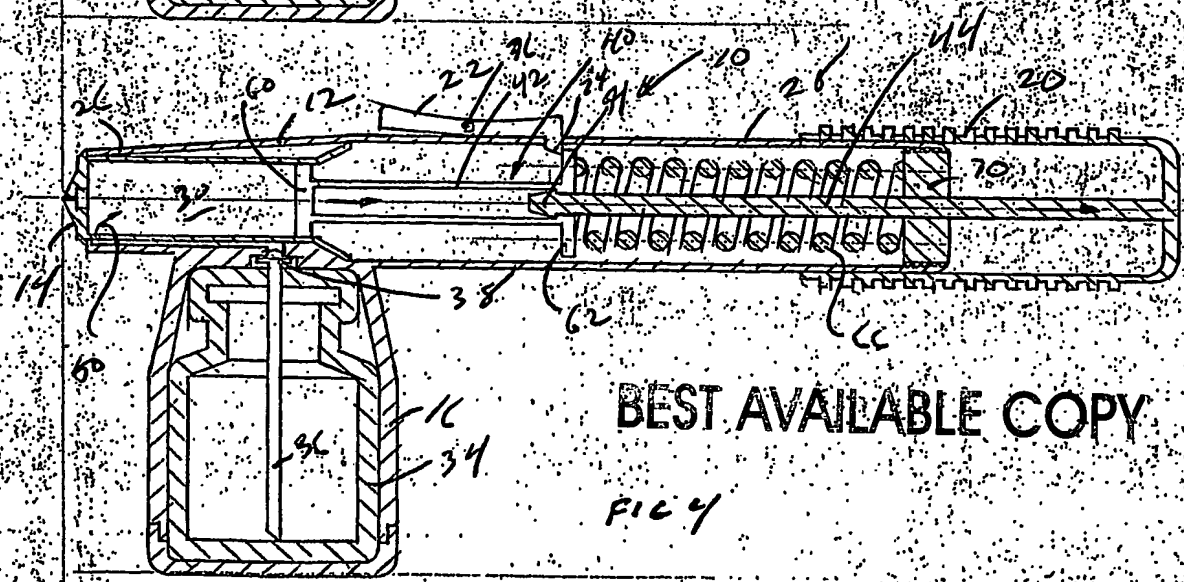


FIG 3



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FIG 4